IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JENNIFER MAITRE, Individually
and as Mother, Guardian and Next Friend
of CHRISTIAN FRANCIS MAITRE, a Minor

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

Civil Action No. 05-CV-10442 (JLT)

PLAINTIFFS' MEMORANDUM IN SUPPORT OF OPPOSITION TO DEFENDANT ELI LILLY'S MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Assume a four-year old boy and his eight-year old sister are playing on the balcony of their apartment house negligently built six years before. Because the builder skimped on reinforced concrete, the structure is unsafe; the balcony collapses and the children are seriously injured. The Defendant Eli Lilly argues that the builder would be required to compensate the girl but not the boy because he was conceived after the negligent act.

The uterus is recognized in obstetrics as a structure and the Defendant's synthetic estrogen is a recognized cause of uterine structural deformity. *See* Gerard S. Letterie, Structural Abnormalities and Reproductive Failure 177-189 (1998) at App. 1.[1] The Defendant, by its failure to test and failure to warn of known risks, built a defective uterus just as a builder might build a defective balcony. The delay in the resultant injury is inherent in the nature of the uterine structure in that it has a thirty-year delay until it is called upon. Christian Maitre has brain damage, resulting in significant physical and mental deficits because he fell 12 weeks early from his mother's DES-caused, stunted uterine structure. *See* Medical Report of the Treating Obstetrician, David Hagen, M.D., September 29, 2003 at App. 12; Report of the Neurological Pediatrician, Yuval Shafrir, M.D., April 6, 2006 at App. 13.

Diethylstilbestrol ("DES") was a mid-20th fertility nostrum. It has been banned by the Food and Drug Administration, recalled by the manufacturers and branded a carcinogen and teratogen by the World Health Organization, the National Institutes of Health (NIH), the American College of Obstetrics and Gynecology, and every health organization devoted to reproductive medicine. *See* App. 1 & 4. Even Defendant Lilly admits that manufacturing DES was a mistake. *See* National Cancer Institute, National Institute of Child Health and Human

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1 All references to "App __" refer to appendices attached to Affidavit of Aaron M. Levine, Esq. Regarding Authentication of Documents, filed herewith.

Development, National Institutes of Health, Were You Born Between 1938 and 1971 or Pregnant Then? If So, You Could Be Exposed to DES (Jan. 1995) at App. 2; *see also* CDC Resource Focuses on DES Exposure, 289 J. Amer. Med. Assn. 1624 (2003); Orenberg, DES: The Complete Story (St. Martin Press 1981); Seaman, The Greatest Experiment Ever Performed On Women (Hyperion Press 2003); Daughters At Risk: A Personal DES Story (Doubleday 1981). The drug was sold to five to ten million women as a universal remedy to produce plump and healthy babies even though it never worked.[2] *See* W.J. Dieckmann et al., Does the Administration of Diethylstilbestrol During Pregnancy Have Therapeutic Value?, 66 Amer. J. of Ob. and Gyn. 1062, 1074 (1953) at App. 5. The Defendant failed to conduct a single test to investigate the DES effect on the forming female daughter even though they knew since the 1940s of reports in the literature that estrogen and DES in high doses stunted the reproductive organs of the exposed daughter in animals (*see* Apps. 3, 4) and would likely cause disruption of that offspring's ability to hold a pregnancy to term.

Plaintiff submits a listing of fifty-seven articles (App. 8) in the medical literature which by their titles reflect that by 1963, it was accepted scientific knowledge that synthetic estrogens, (1) were more potent than natural estrogens (*see* Chen, K.K., The New Synthetic Estrogen, Stilbestrol, Quarterly Bulletin Indiana University Medical Center 15 (1941) at App. 9); (2) could pass through the umbilicus of a recipient mammalian mother into the forming daughter; and (3) target her reproductive tract (cervix & uterus), causing malformation, abortion or premature birth. Nonetheless, defendant conducted no investigation of this foreseeable eventuality nor

2 In 1968 the National Academy of Sciences in its review of the effectiveness of DES for the purpose of preventing threatened or habitual abortion found that effectiveness cannot be demonstrated by the literature or its own experience. *See* Regulation of Diethylstilbestrol (DES) (Its Use As a Drug for Humans and in Animal Feed): Hearing Before the Subcomm. of the H. Comm. on Government Operations 92nd Congress 77 (1971). At that time Lilly was asked by the FDA to provide evidence that DES was effective and failed to provide any such information.

warned of its lack of testing. Furthermore, prior to Lilly's promoting DES to Plaintiff Jennifer Maitre's mother's doctor, there were over ten reports published that DES would cross the placenta and alter the structure of the exposed fetus' reproductive tract in animals. In 1959 (four years before Jennifer Maitre was injured), researchers in Philadelphia and at NIH reported actual malformation in a DES daughter. *See* Alfred M. Bongiovanni et al., Masculinization of the Female Infant Associated with Estrogenic Therapy Alone During Gestation: Four Cases, 19 J. Clin. Endo. & Metab. 1004 (1959) at App. 7. Lilly admits in this case that it failed to conduct a single controlled test to determine the effects of DES on offspring in the face of these reports. At that time, it certainly did not take a rocket scientist to realize that a DES daughter's stunted uterus may not be able to hold a pregnancy to term thirty years later.

IV. PLAINTIFFS' RESPONSE TO DEFENDANT'S STATEMENT OF MATERIAL FACTS

1-3. Admitted.

4. Denied. Defendant's DES stunted Jennifer Maitre's forming reproductive tract, (ultimately the shared organ of her child, the infant Plaintiff). Christian Maitre, as an oocyte in his mother's developing ovaries, was actually exposed to DES and doomed to suffer its effects.

Plaintiffs' Counter Statement of Facts

5. In 1953, esteemed researchers reproduced and reported a stunted uterus in mammalian daughters exposed to DES *in utero*. *See* R. R. Greene, M. W. Burrill & A. C. Ivy, Experimental Intersexuality: the Paradoxical Effects of Estrogens on the Sexual Development of the Female Rat, 74 The Anatomical Record 4 (1939) at App. 4. Defendant admits it never investigated this effect in animals or in humans.

6. In 1947, Rosenblum and associates raised the following critical questions as to the efficacy of DES for pregnant women (which Lilly completely ignored): (1) whether large dosages of DES are unsafe to pregnant women, (2) how DES affects the glandular balance of the child in utero (it malformed the child's uterus), (3) does DES work better than other drugs in preventing miscarriage? Gordon Rosenblum & Eugene Melinkoff, Preservation of the Threatened Pregnancy with Particular Reference to the Use of Diethylstilbestrol, 55 West J. Sur. Obst. & Gyn. 597 (1947) at App. 6. Lilly never investigated or answered these questions.

7. In 1950, Enders reported that female minks who consumed DES in their feed (chicken waste) were unable, or barely able, to reproduce. Further, that the kits born from those minks had ovaries "injured beyond recognition." Robert K. Enders & William L. Merritts, Mink Production in Relation to Stilbestrol, 16:7 The Fur Journal 4 (1950) at App. 3.

8. In 1953, Dieckman and associates at the University of Chicago, conducted the first controlled double-blind prospective test of the efficacy of DES, concluding that it was ineffective in preventing the accidents of pregnancy, as there were more births in the women who were not exposed to DES than in the controlled group of DES exposed women. *See* App. 5.

9. All of Christian Maitre's injuries are a result of his birth uterus' exposure to DES. Report of David F. Hagen, M.D., at App. 12; Report of Yuval Shafrir, M.D., at App. 13; Report of Merle J. Berger, M.D., at App. 14.

10. There were at least 57 articles in the scientific literature that were published before the DES exposure in this case in 1963, which should have alerted a reasonably prudent manufacturer to the propensity of estrogen or synthetic estrogen to stunt the forming female's uterus (*see* List of DES Studies at App. 8) and thereby predispose it to expelling the developing baby prematurely.

11. In 1959, four years before the exposure in this case, Lilly was on notice of the propensity of DES to cause malformations in the human daughter exposed *in utero*. See Bongiovanni at App. 7. The infant Plaintiff's pre-term birth was foreseeable. See Statement of Harris Busch ("Busch Statement") at App. 10.

12. Defendant Lilly as an international pharmaceutical company holds itself out as a leading expert of the world's literature regarding the drugs they promote.

13. Tests, animal and human models, and diagnostic equipment were available by 1963 to determine whether DES given to pregnant women would have had an adverse effect on the exposed daughter's uterus. (Busch Statement at App. 10.)

V. DEFENDANT HAS NOT MET ITS BURDEN FOR SUMMARY JUDGMENT

A. Summary Judgment Standard

Summary judgment is appropriate only where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Carroll v. Xerox Corp., 294 F.3d 231, 236-37 (1st Cir. 2002). All reasonable inferences are to be made in favor of the non-moving party. Davila-Rivera v. Caribbean Refrescos, Inc., 150 F. App'x 3, 6 (1st Cir. 2005). Furthermore, while "litigants may not offer speculations or slight possibilities in support of their claims" they are also not limited to offering only the incontrovertible. Shields v. Eli Lilly & Co., 895 F.2d 1463, 1467 (D.C. Cir. 1990). Thus, the Court must view the law in a light most favorable to the Plaintiff when deciding a Motion for Summary Judgment. At this stage in the proceeding Plaintiff is entitled to the presumptions that Lilly (1) knew the risk of preterm birth to the future child of the DES daughter,

(2) negligently failed to test and failed to warn, (3) over-promoted DES without any safety or efficacy testing and (4) knew that DES was ineffective and of no value.

B. Massachusetts Law Provides Compensation for Preconception Torts

1. Defendant's Authorities

None of the Massachusetts decisions cited by Defendant concern the rights and obligations of DES preterm babies, or even come close to, the issue in this case, i.e. the right of a preconceived child to sue for an injury caused by a tortfeasor's action where the child was directly injured by the Defendant's wrongful conduct. All of the Massachusetts decisions cited concern claims for loss of consortium for emotional injuries and are totally irrelevant to the Maitre scenario.

In Angelini v. OMD Corp., 410 Mass. 653, 575 N.E.2d 41 (1991), the court did not even consider an action by a preconceived child for his injury – the child had already been conceived. The child in Angelini was suing for loss of consortium for his father's injuries that occurred before he was born. Id. at 653. Lareau v. Page, 39 F.3d 384 (1st Cir. 1994), had nothing to do with a preconception complaint by a physically injured child. There, the court strictly followed Angelini in denying the right of a child's action for loss of consortium for her mother's brain injury. The court never discussed the viability of a preconception claim by a child who has been physically and personally injured by a Defendant's conduct.

While the court in McNulty stated that it would not rule on the preconception right of an injured child, it clearly upheld the viability of a preconception tort if justified by the facts of the case. McNulty v. McDowell, 415 Mass. 369, 373, 613 N.E.2d 904 (1993). In that case the court ruled the defendant had no duty of care toward the preconceived child because the child's mother failed to establish a patient-physician relationship with the tortfeasor, her gynecologist. Id. If

she had established his duty, the physician would have been required to administer rubella shots, thereby preventing the resulting injuries that afflicted her fetus. Id.

2. Lilly's Appellate Authorities Are Neither Persuasive Nor Binding

Lilly misrepresents the state of the law regarding DES decisions. *See infra*. There are in fact five DES decisions finding in favor of the child. The decisions Lilly cites are based on different facts, different times and different issues.

Lilly's reliance upon Enright is misplaced for a number of reasons. *See* Enright v. Eli Lilly & Co., 77 N.Y.2d 377, 570 N.E.2d 198 (N.Y. 1991). First and foremost, Massachusetts has specifically *declined* to adopt the rule in Enright. McNulty, 415 Mass. at 373 (declining to adopt the bright line rule in Enright). The Court so held because Enright adhered to the New York Albala rule which precluded any preconception tort claims whatsoever in the state of New York. Albala v. New York, 54 N.Y.2d 269, 429 N.E.2d 786 (N.Y. 1981). In its bright-line preclusion of all claims for prematurely born injured children from DES the Enright court proceeded on two bases: (1) *stare decisis* based on New York law and (2) the New York policy determination that DES defendants should enjoy the same even-handed treatment as the defendant physician in Albala. Enright, 77 N.Y.2d at 388.

Unlike the instant case, Enright was a strict liability case in which negligence based on foreseeability was not even considered. Christian Maitre herewith waives strict liability. The opinion in Enright erroneously asserted that the injurious effects from DES exposure could extend for generations as a "rippling effect," and consequently, it had to set what the court itself acknowledged were "artificial and arbitrary" boundaries. Id. at 387. The court was concerned about the genetic effects of DES, and that generations upon generations of those affected with the now-defunct gene would be able to sue in tort. Here, the Plaintiff does not allege any

genetic, chromosomal, or generational risk nor can the Defendant raise such a risk. Indeed, neither the Plaintiff nor the Defendant has offered proof of such a risk. Christian Maitre was injured from a DES-caused T-shaped uterus incapable of carrying him to full term, an injury where his brain came into the world "raw" because his birth uterus was a DES-damaged oven. His injury is not genetic; it is environmental. Enright's "rippling effect" concerns do not apply to this case.

Courts today do not follow Enright even in New York. The Second Circuit interpreting New York law held that third generation DES claims could be the basis of liability in contravention of Enright. The Second Circuit sided with the majority of jurisdictions, including those that characterize New York's approach as "draconian" and stated that DES preconception torts could be the basis of liability. E.R. Squibb & Sons, Inc. v. Lloyd's & Cos., 241 F.3d 154, 171, n. 6 (2d Cir. 2001), at App. 15, *citing* Lough v. Rolla Women's Clinic, Inc., 866 S.W.2d 851, 853-54 (Mo. 1993) (characterizing New York's approach as "draconian" and holding that "'preconception torts' can be sensibly analyzed under existing principles of tort law").

Defendant's second case, Grover v. Eli Lilly & Co., 591 N.E.2d 696 (Ohio 1992), closely followed Enright and is fully distinguishable from this case. The plaintiff in Grover failed to provide any proof of proximate cause which would link Lilly's breach of duty to the child's injury. 591 N.E.2d at 700. Unlike the present case, however, Grover's DES daughter was exposed *in utero* in 1952 before the publication of major studies linking DES with reproductive anomalies. Accordingly, the Grover court was not shown nor did it consider the overwhelming scientific evidence available to Lilly in 1963 that proves as foreseeable any resulting premature injury to the children of DES daughters. In other words, what was perhaps unforeseeable to Lilly

in 1952 had become foreseeable eleven years later when Jennifer Maitre was exposed to DES *in utero*, after further studies were made public.

Even at the time, Grover was not a non-controversial opinion. The court split 4-3 on the issue. The dissenting judges wrote a vigorous dissent in which they argued that:

> ... It would appear that DES manufacturers knew or should have known that the human fetus exposed *in utero* might have a defect in the female reproductive system. Additionally, is it not then foreseeable that that female fetus would at some point seek to employ the defective reproductive system? The answer must be a resounding "yes." ... What could have a more direct causal connection than a premature birth by a woman who was known to have an incompetent cervix? From this it becomes readily apparent that DES grandchildren were a foreseeable group of plaintiffs.

Id. at 703, n. 4 (Resnick, J., dissenting). Three of the Grover court judges found a cause of action for DES grandchildren even though the exposure in that case occurred in 1952, before much major testing on the drug, and the Plaintiff failed to present evidence of proximate cause. How many more judges would have ruled for the Plaintiffs had the exposure occurred in 1963, where *fifty-seven* studies indicated that DES was harmful, and the plaintiff had presented evidence of foreseeability and proximate cause?

Defendant's third inapplicable case, Renslow v. Mennonite Hospital, 67 Ill. 2d 348, 367 N.E.2d 1250 (Ill. 1977), in a peculiarly Illinois setting, decreed that liability extending to a new class of victims can only apply prospectively. Importantly, the court emphasized that "nothing in its opinion" spoke to the issue of whether a pharmaceutical manufacturer is liable for injuries suffered by preconceived grandchildren. Id. at 394 (Greiman, J., specially concurring) (objecting to any "unnecessarily premature cut-off of claims by DES grandchildren," and agreeing that "logic and sound policy require a finding of a legal duty in this case"). For this reason, the

Renslow decision actually supports finding a cause of action for preconception torts. Indeed, it has been widely cited for such a proposition.[3]

Lilly cites Sparapany v. Rexall Corp., 618 N.E.2d 1098 (Ill. App. 1993), for its rejection of the cause of action by preconceived children. The decision does not stand for such a proposition, but did reiterate that, based on the Illinois holding of Renslow, that preconception torts committed prior to August 8, 1977 were effectively barred in Illinois. Sparapany, 618 N.E.2d 1098. The court was again careful to note that nothing in its opinion spoke to the issue of whether a pharmaceutical manufacturer can be held liable for injuries allegedly suffered by grandchildren, yet unconceived, of an individual who has ingested a drug subsequent to the relevant date. Id. at 1101-1102.

3. Recovery For Preconception Torts Is Established Law In America

Lilly ignores the prevailing common law rule that a preconception cause of action is viable as a matter of right. *See* Jorgensen v. Meade Johnson Labs. Inc., 483 F.2d 237, 240 (10th Cir. 1973), (tortious conduct occurring prior to conception should be actionable for an infant injured from a defective food product manufactured before his conception or he would be without remedy); Lough v. Rolla Women's Clinic, Inc., 866 S.W.2d 851, 854 (Mo. 1993), explaining the absurdity of an absolute bar against preconception recovery illustrated by the following scenario:

> Assume a balcony is negligently constructed. Two years later, a mother and her one-year-old child step onto the balcony and it gives way, causing serious injuries to both the mother and the child. It would be ludicrous to suggest that only the mother would have a cause of action against the builder, but because the infant

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3 *See* Lynch v. Scheininger, 162 N.J. 209, 223, 744 A.2d 113, 121 (2000); Grover v. Eli Lilly & Co., 63 Ohio St. 3d 756, 759, 591 N.E.2d 696, 698 (Ohio 1992); Enright v. Eli Lilly & Co., 77 N.Y.2d 377, 570 N.E.2d 198 (N.Y. 1991) (Hancock J., dissenting); Siemieniec et al. v. Lutheran General Hospital, 117 Ill. 2d 230; 512 N.E.2d 691 (1987); Anastasia Enneking, The Missouri Supreme Court Recognizes Preconception Tort Liability: Lough v. Rolla Women's Clinic, Inc., 63 UMKC L. Rev. 165 (1994).

> was not conceived at the time of the negligent conduct, no duty of care existed toward the child. It is unjust and arbitrary to deny recovery to [a child] simply because he had not been conceived at the time of [the] negligence.[4]

Thus, the great weight of authority in America trends toward the recognition of preconception torts. We are, of course, interested in what *Massachusetts* law has to say about such torts since state substantive law must be applied by a federal court sitting in diversity jurisdiction. Reicher v. Berkshire Life Ins. Co. of Am., 360 F.3d 1,4 (1st Cir. 2004) (citing Erie R.R. Co. v. Thompkins, 304 U.S. 64, 78 (1938)). The Massachusetts Supreme Court would uphold a DES preterm birth injury. *See infra* ch. 5. But, there is no conclusive law on the general validity of preconception torts in the Commonwealth. Thus, it is likely that Massachusetts, were it to rule upon the validity of such claims, would rule with the great weight of American authority and find a cause of action for preconception tort claims, rather than with minority jurisdictions.

4. Courts Have Held a Preconception Tort Claim Exists in DES Cases

Lilly neglects to mention that at least three trial courts and two appellate courts have ruled that children born prematurely from daughters exposed to DES have cognizable claims. E.R. Squibb, 241 F.3d at 169, at App. 15; McMahon v. Eli Lilly & Co., 774 F.2d 830 (7th Cir.

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4 *See* Walker v. Rinck, 604 N.E.2d 591 (Ind. 1992) ("[n]o one would seriously contend that an infant could not recover for injuries sustained as a result of a defective product manufactured prior to the conception of the infant"); Bergstreser v. Mitchell, 577 F.2d 22, 25, n.4 (8th Cir. 1978) (noting that the great weight of authorities in America are overwhelmingly favorable toward recognizing a cause of action for preconception injury"); Lynch v. Scheininger, 744 A.2d 113, 127 (N.J. 2000) (holding that preconception torts are actionable in negligence claims); Graham v. Keuchel, 847 P.2d 342, 365, n. 125 (Okla. 1993) (noting that "[t]he negligence was actionable since defendants could foresee that . . . the substandard conduct could harm a later-conceived child"); Pitre v. Opelousas Gen. Hosp., 530 So.2d 1151, 1157 (La. 1988) (holding that a tortfeasor "owes a duty to the unconceived child as well as to its parents"); Monusko v. Postle, 437 N.W.2d 367, 369-370, appeal denied 433 Mich. 869 (Mich. 1989) (holding "that defendants owed a duty to the plaintiff, even though she was not conceived"); McAuley v. Wills, 303 S.E.2d 258, 260 (Ga. 1983) (holding that, in some situations, a person should be under a duty of care toward an unconceived child); *see generally* Int'l Union, et al. v. Johnson Controls, Inc., 499 U.S. 187, 213 (1991) (White, J., concurring) (stressing that many courts have recognized a right to recover for prenatal injuries caused by preconception torts, citing 3 F. Harper, F. James & O. Gray, Law of Torts §18.3, at 677-78, n.15 (2d ed. 1986)); Renslow v. Mennonite Hosp., 367 N.E.2d 1250, 1254-55 (Ill. 1977) (holding that a defendant may be held liable to a person whose existence was not apparent at the time of his act).

1985), at App. 16; Murchison v. Eli Lilly & Co., No. H-88-927 (S.D. Tex 1991), at App. 21; Sorrells v. Eli Lilly & Co., No. 60386 (MD. Cir. Ct. Mont. County 1990), at App. 20; DeMayo v. Schmitt, 5 Pa. D. & C.4th 197 (Pa. Commw. Ct. 1989), at App. 18. Hoping to forestall any further liability, Lilly has strategically declined to appeal any of those decisions to a higher court. In McMahon, the Illinois appellate court reversed a lower court's directed verdict for the defendant, holding that a jury could find that it was sufficiently foreseeable that Lilly knew or should have known that DES might cause reproductive abnormalities, such as prematurity, in the female offspring exposed to DES during pregnancy. 774 F.2d at 834, at App. 16. McMahon noted the significance of experimental data prior to 1955 demonstrating that "exogenous estrogens (including DES) could cause physical abnormalities in the reproductive tracts of animals exposed to the drug *in utero*." Id.

The DeMayo court also rejected the defendant manufacturer's motion for summary judgment, explaining that "if proper animal tests or other research would have shown genital defects in offspring of DES mothers, it would not be unforeseeable that those genital problems could result in premature births and other defects in the grandchildren." DeMayo v. Schmitt, 5 Pa. D. & C.4th at 200, at App. 18. The court in DeMayo concluded, *inter alia*, that "the most reasonable way to approach the problem is to allow recovery for the third generation if the manufacturer negligently failed to learn of genital-tract injuries to the second generation." Id.

The trial court in Sorrells denied summary judgment for Lilly, finding persuasive plaintiff's argument that the claim was not too remote, and that her injuries were the proximate result of an organ that was malformed due to DES exposure. *See* Sorrells, No. 60386 (MD. Cir. Ct. Mont. County 1990), Bench Order at 32, at App. 20.

Murchison similarly allowed third-generation recovery to children harmed by DES, stating that the claim is not remote in that many years pass before the injury becomes known to the DES daughter and that, "DES claims are simply different from other tort claims, even other preconception tort claims, in that the damage allegedly caused by DES does not manifest itself until the fetus exposed to the drug becomes a mother." Murchison, No. H-88-927 (S.D. Tex 1991) Mem. & Order at 8, at App. 21. The court sided with the plaintiff, finding that there would be no "rippling effects" because there was no evidence of genetic damage to the prematurely born child. Id.

Moreover, the court in Taylor v. Cutler also expressed its approval of third generation DES claims, stating:

> [D]ecisions that have recognized or suggested preconception liability in the context of product liability actions, [especially when those] cases have involved the imposition of liability on drug manufacturers of diethylstilbestrol ("DES") for injuries caused to the offspring of women exposed to the drug. [In] those cases, DES was administered to pregnant women to help prevent miscarriages. Female children of mothers who ingested DES (second-generation offspring) and their children (third-generation offspring) have suffered from reproductive problems ranging from infertility to cancer. [The] drug manufacturer's knowledge in producing the drug is inextricably related to the mother's reproductive capacity. Thus, based on the manufacturer's testing of the product, research, and knowledge, the company knew, or should have reasonably perceived, that potential side effects of the drug may cause harm to the mother's future offspring.

703 A.2d 294, 301-02 (N.J. Super. Ct. App. Div. 1997), at App. 20.

Lastly, the Second Circuit refused to follow Enright and upheld the District Court's ruling in a DES setting. E.R. Squibb, 241 F.3d at 169, at App. 15. The court stated that "the third-generation claimants' injuries are covered because they were causal consequences of 'occurrences' – *in utero* injuries-in-fact to the reproductive systems of the second DES generation." Id.

5. Massachusetts Has Signaled Its Willingness to Entertain Preconception Tort Claims

Contrary to Defendant's argument, the Massachusetts Supreme Judicial Court declared itself open to the imposition of a preconception duty by stating that "cases involving different allegedly wrongful preconception conduct might well yield different results." McNulty, 415 Mass. at 374 n.6. McNulty also pointed out that other courts have not been persuaded by the conclusion that preconception torts should be barred absolutely. Id. (citing with approval cases upholding the preconception right, including Walker v. Rinck, 604 N.E.2d 591, 595 (Ind. 1992) and Doolan v. IVF Am., Inc., et al., 12 Mass. L. Rep. 482 (Mass. Super. Ct. 2000) (noting that a claim arising from a preconception tort "is not foreclosed under Massachusetts law," and distinguishing the "wrongful life" action before it from those preconception actions deemed cognizable in other jurisdictions in which "the negligence of the defendant caused the minor plaintiff to be born with severe defects, when he/she would have otherwise been born healthy.")). Furthermore, in Payton v. Abbott Labs, 386 Mass. 540, 437 N.E.2d 171 (1982), the Supreme Judicial Court declared that Massachusetts law allowed claims brought for injuries sustained by a non-viable fetus as a result of it's mother's ingestion of drugs. Id. at 565 (holding that "a right of action [is] available to a plaintiff whose mother ingested the drug ... assuming that it is not established that the fetus was probably viable at the time of the injury").

C. CHRISTIAN MAITRE'S ACTION IS NOT REMOTE

Lilly argues that Christian Maitre cannot demonstrate that Lilly ever owed him any duty, that his injury was "too remote," because it was not reasonably foreseeable when Lilly sold DES that those pills would cause his injuries. [Def. Mem. 14]. This is a classic jury question. In addition to scientific studies, the Plaintiffs will present the testimony of two eminent scientists, the chair of the Toxicology Department at Baylor and an OB/GYN professor at George

Washington University, who will state that it was, as a matter of fact, foreseeable in 1963 that a Christian Maitre-type scenario would follow from his mother's prenatal DES exposure. *See* Busch Statement, at App. 10; Statement of Richard J Falk, M.D., at App. 11. The Plaintiffs' experts are entitled, at this stage, to be given every reasonable inference and to be believed. Preterm births by DES injured daughters are not such a remote fluke as the facts in Palsgraf – they happen over and over again. Palsgraf v. Long Island R. Co., 162 N.E. 99 (N.Y. 1928).

D. LILLY OWED A DUTY OF CARE TO CHRISTIAN MAITRE BECAUSE HIS INJURIES WERE REASONABLY FORESEEABLE

It has long been held in Massachusetts that tortfeasors have a duty to those foreseeably placed at risk by their misconduct and who come proximately to harm. Fithian v. Reed, 204 F.3d 306, 309 (1st Cir. 2000) (noting that, under a reasonable care standard, defendants have a "duty to prevent foreseeable injury"); Whittaker v. Saraceno, 418 Mass. 196, 198, 635 N.E.2d 1185 (1994) (noting that foreseeability limits the duty of care and proximate cause). Negligence questions involving issues of what is reasonably foreseeable are ordinarily left to the jury. Glick v. Prince Italian Foods, Inc, 25 Mass. App. Ct. 901, 903, 514 N.E.2d 100, 102 (1987). Only where no rational view of the evidence would warrant a finding of negligence may a court find, as a matter of law, that the Plaintiff's injuries were not foreseeable by the defendant. Id. In determining foreseeability, this Court must review what was, or should have been known, to Lilly prior to 1963. Whittaker, 418 Mass. at 199 (holding that all of the circumstances are examined in defining the scope of a duty of care based on the reasonable foreseeability of harm).

E. LILLY'S DES DRUG PROXIMATELY CAUSED CHRISTIAN MAITRE'S INJURIES

While foreseeability concerns itself with whether it is reasonable from Defendant's vantage point that its harmful conduct may injure another *at the time it sold its drug*, causation is

the narrower question of whether its dangerous drug can be shown to have brought about Plaintiff's injury. *See* Reports of Medical Experts, at Apps. 12-14; Payton, 386 Mass. 540, 437 N.E.2d 171 (holding that causality is the narrow question of whether the plaintiff can prove that a particular defective drug directly caused his injury).

In the instant case, it is uncontested that Christian's injury is the direct consequence of his mother's exposure to DES. Mary Susan Bane ingested DES manufactured by Lilly while she carried Jennifer Maitre *in utero*. DES containing massive amounts of estrogen stunted the normal embryonic development of Jennifer Maitre's uterus and cervix, causing her uterus to become hypoplastic and T-shaped, and her cervix undeveloped and immature. *See* Reports of Medical Experts, at Apps. 12-14. Years later, Jennifer Maitre conceived Christian in her T-shaped uterus with an incompetent cervix. Her cervix became Christian's organ for 28 weeks. Id. Because this shared organ had limited expansion capability, Christian was born after only 28 weeks of gestation, and consequently, suffers from severe fine and gross motor deficits and cortical dysfunction. Id. Had Jennifer Maitre not been exposed, it is more likely than not that Christian would have gone to term and not been injured. The nexus between DES and Christian Maitre's injury, between his mother's malformed uterus and cervix and his prematurity, is proximate with respect to space and time.

The Supreme Judicial Court in Payton, considering the question of whether Lilly was liable for harm caused by DES to the child *in utero* (it was), emphasized the efficacy of the finder-of-fact in reviewing the evidence and determining the sufficiency of causation, finding that the plaintiff had the right to prove his case in court. 386 Mass. at 562. Payton considered the very same argument Lilly raises now, that "recovery should not be allowed because of the practical difficulty of proving causation." Id. The court asserted that medicine and science had

made advances "that take care of these arguments," where the plaintiff could show causation through "objective tests," expert witnesses, and scientific exhibits and studies. Id. at 562-563. Unlike emotional harms, the court stated it was "convinced" that there should be no bar to plaintiff's action for "injuries that can be demonstrated to exist by medical evidence, and *for all harm to the plaintiffs that is naturally and reasonably related to those injuries*." Id. at 563 (emphasis added). Indeed, Payton chronicled a number of cases in Massachusetts history, noting the clear legal trend in favor of permitting recoveries based on advances in objectively proven theories of causation. Id. Agreeing with Payton, the court in Renslow proclaimed its confidence that when a preconception case is presented, "the judiciary will effectively exercise its traditional role of drawing rational distinctions, consonant with current perceptions of justice, between which injuries are compensable and those which are not." Renslow, 367 N.E.2d at 1255.

F. RECOGNIZING LIABILITY IN PRECONCEPTION DES CASES IS MANAGABLE

In jurisdictions that have recognized, or expressed a willingness to recognize preconception torts, there have been no floods of litigation. Lough v. Rolla Women's Clinic, 866 S.W.2d 851, 853-54 (Mo. 1993) (finding "no indication that the states permitting preconception torts have been swallowed by ... [an] apocalypse of liability actions"); Julie A. Greenberg, Reconceptualizing Preconception Torts, 64 Tenn. L. Rev. 315, 342 (1997) (commenting that there has been no flood of litigation in states that have recognized preconception torts).

G. CHRISTIAN MAITRE'S ACTION WOULD NOT DETER BENEFICIAL DRUGS FROM THE MARKET

Lilly claims that allowing Christian Maitre's cause of action would have a "detrimental effect on research and development of new and useful drugs" without a single supporting

authority or fact. (Def. Mot. at 9.) Lilly simply makes the bare assumption that somehow compensating Christian will sound the death knell of research for new or helpful products. Lilly misleads this Court by offering selected quotes from their citations by asserting that courts only consider the policy dangers of "over-deterring" drug companies from distributing useful drugs into market. In fact, Massachusetts courts are equally, if not more, concerned with deterring the marketing of defective products. Haglund v. Philip Morris, Inc., 446 Mass. 741, 847 N.E.2d 315, 321 (2006), *citing* Correia v. Firestone Tire and Rubber Co., 388 Mass. 342, 354-355, 446 N.E.2d 1033 (1983), *quoting* Restatement (Second) of Torts § 402A cmt. c (1965) (holding that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons ... are those who market them . . . ."). As the Supreme Court of Rhode Island aptly puts in another DES case:

> Although it may be argued that the imposition of potential liability on defendant in this case would discourage drug manufacturers from producing or advancing other types of drugs in the future, we believe the more enlightened view is that this sort of liability will encourage drug companies to produce and market *safe* drugs.

Anthony v. Abbott Labs, et al., 490 A.2d 43, 48 n. 3 (R.I. 1985).

In Blankenship v. Gen. Motors Corp., 406 S.E.2d 781 (W.Va. 1991), the court *expanded* comparative accident liability against General Motors for defective automobile design after considering the public policy considerations of deterring defective products against any possible "over-deterrence." 406 S.E.2d at 783. The Court noted that "...most large companies with established products consider product liability a minor annoyance," id., and held that, in the type

of case before it (crashworthiness) West Virginia would always apply the rule most favorable to the plaintiff, if there was a split of authority on an issue. Id. at 786. The purpose of such liability, the court found, is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves. Id. at 784. Faced then with competing policy considerations, the court found for the plaintiff, and held that the cost of injuries caused by defective products was better born by the manufacturer.

Payton similarly balances public policy arguments, but in the context of whether to expand DES liability to a market share analysis in product identification. Payton, 386 Mass at 574. Critical to the Payton Court, was the idea that innocent parties would be held liable for actions they, by definition, did not commit. Id. The court rejected the market share theory as an "over-deterrent" then, because those innocent parties would be liable even if they could prove their innocence. This differs dramatically from the preconception tort context, where it has not been contested that Lilly is, in fact, at fault for causing Christian's injuries. There is no danger here of holding a defendant liable for actions it did not commit; consequently, there is no fear of "over-deterrence." In point of fact, pharmaceutical companies will continue manufacturing drugs, regardless of the potential for legal liability. Pharmaceutical manufacture is a high-risk high-profit business. In 2001, the ten pharmaceutical companies in the Fortune 500 posted higher profits ($35.9 billion) than the other 490 companies combined ($33.7 billion).[5] These profits were posted in spite of the liability that drug companies may be exposed to. In light of these numbers, some courts have expressed the concern that, far from discouraging drug companies from developing new drugs, liability for bad products merely helps to ensure that *safe*

5 Marcia Angell, The Truth About Drug Companies: How They Deceive Us and What to do About It, 14 (2004), at App. 17.

drugs are placed on the market. Anthony, 490 A.2d at 48 n. 3. Indeed, on December 21, 2005 Lilly pleaded guilty to a criminal charge of over-promoting its drug Evista and agreed to pay $36 million for a criminal fine. U.S. v. Eli Lilly & Co., No. 05-1884 (S.D. Ind. 2005). Defendant's claims of lack of funds for research should be viewed with their expenditures for lobbying, television advertising and criminal fines. The liability imposed today may ensure that unsafe, untested and ineffective drugs will never harm *this* generation's grandchildren.

VI. CONCLUSION

For the reasons set forth, Defendant Lilly's motion for summary judgment should be denied.

Respectfully submitted,

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Dated: July 28, 2006

CERTIFICATE OF SERVICE

I, Erica Tennyson, hereby certify that this Plaintiff's Memorandum in Support of Opposition to Defendant Eli Lilly's Motion for Summary Judgment, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on July 28, 2006.

/s/ Erica Tennyson
Erica Tennyson